APPENDIX G
The Ovarian SPORE Database

The database of the Ovarian SPORE will operate as a node of our overall CHTN database (Tissue Resource Data Management System (TRDMS)). Version 2 of the TRDMS, described subsequently, has completed alpha testing and is in beta testing. Version 2 of the TRDMS represents a major advance in programs devoted to operating and managing tissue resources, so this program will be offered to other tissue resource organizations at the cost of transfer. We also will demonstrate the program at educational sessions.

Improvements in Version 2 of TRDMS include an archival function to clear Version 2 of unneeded data that ultimately may slow operation of the system. Multiple new investigator and donor fields have been added based on experience. Navigation through the database was improved to make utilization patterns more consistent, the TRDMS more user friendly and data entry faster. Finally, the TRDMS was modernized by modeling it on a windows format so that each page of the database has consistent menu bars and pull-down menus. Just as the investigator part of the TRDMS was improved, so was the donor/specimen tracking layer in order to improve navigation, modernize its design to a windows format, add fields, and improve quality control functions.

The new version of the TRDMS is programmed in Visual FoxPro to permit easy programming support. It has a windows motif with menu bar and pull down menus. It has been designed with a common navigation sequence, common commands, and specific hot keys to be very user friendly and to minimize the chances of data entry errors. The system works with mouse and/or keyboard commands and forward and backward cursor movements are easy. The information included in the program is that considered by the CHTN personnel to be necessary for interactive communications with investigators, and for providing NCI with needed data as to day to day operations of tissue resources. The new version of the TRDMS can be considered to be composed of multiple (four) interacting layers – investigator, donor/ specimen tracking, networking and shipping/billing. The four layers work together so that tissue requests are filled efficiently and so that requests for tissues that cannot be met promptly (i.e. within several weeks) are networked to all divisions so that each division immediately knows all unique aspects of the tissue request and is ensured that the researcher making the request has fulfilled all requirements (e.g., has agreed to our biohazard educational requirements). Networking and billing functions will not be utilized by the Ovarian SPORE component (node) of the program. Ultimately, the overall program aids in efficiently matching tissue requests with tissue collections, aids in providing the tissues promptly to investigators, maintains shipping records, generates the invoice in order to bill the investigator for tissue, keeps track of unpaid investigator balances as well as refusals of tissue, and provides an inventory including storage locations of tissues being temporarily stored for specific investigators.

The investigator layer has all the administrative information needed to provide tissues to the investigator including primary and secondary shipping/billing addresses, IRB approval, laboratory contacts, preferred courier, and extra-and intra-mural funding needed for priority assignment, as well as the exact details of the tissues needed – diagnosis, number, type, site, size, processing requirements (e.g., snap-frozen in liquid nitrogen), and tissue and therapeutic restrictions, (e.g., age, race, gender, concomitant diseases such as diabetes; exclusion of prior radiation therapy). An abstract of the proposed research is included in the database to aid in better serving requests by, for example, suggesting other tissue sites/sources; the program permits the abstract and other information to be scanned into the database. The database also has an investigator contact history and a history of tissues supplied to each investigator.

Version 2 of the TRDMS permits each investigator to have multiple research projects (e.g., a study of ductal carcinoma in situ [DCIS] of the breast and a separate project to study ovarian carcinomas). Multiple types of tissues can be collected under each project; for example, under the DCIS project, DCIS, breast cancer, uninvolved breast and normal breast may be collected.

The donor/tissue tracking layer includes all relevant information concerning tissues characteristically needed by researchers, including if the donor has provided informed consent; thus, all types of information needed to match investigator needs and requirements including past therapy with radiation or chemotherapy are

included. Thus, the diagnosis, site and size of the tissue sample are specified as well as the age, race and gender of the donor. A separate section of the donor layer is devoted to quality control of research tissues and it includes typically the microscopic diagnosis of an H&E paraffin or frozen section representative of the tissue provided for research including the proportion of necrosis/fibrosis in the specimen. Specific issues relevant to tissue source including whether samples are from autopsy/surgery as well as relevant processing times (time after death) are included in this section as are the specifics of tissue processing (e.g., fresh, minced in RPMI medium with % fetal calf serum). The time when each specimen is assigned and/or transferred to a specific investigator is noted; there is an interactive link between the investigator and donor layers. Investigator requirements to aid in donor tissue assignment are obtained from the investigator section and data on the shipment of specimens are provided to the accounting and investigator components. The donor section also specifies the storage site in the liquid nitrogen or -70° freezers at which specific samples are stored if temporary storage is necessary.

The networking layer is designed to ensure that all tissue requests are served promptly. The networking is based on using a common database that is updated nightly and, in turn, it updates all site databases nightly. Updating the common database relies on rules to prevent collision of data. Nightly updating is based on our experience; the CHTN does not require faster updates, must minimize any interruptions in daily computer operations, and wants to limit on-line time for better security. After an investigator's request has been entered in the computer for three weeks and not filled, the request is automatically networked (shared) with all other divisions. All data needed to service the investigator's tissue requests are transferred to the common networked database and from the common database to individual databases so that the new orders can be added promptly to tissue requests.

Although Version 2 fulfills most of the CHTN's current needs for a TRDMS, we foresee many new developments in internet utilization, changes in databases and desktop hardware, and new tissue needs and increased investigator capabilities of on-line communication; thus, the CHTN must continually adapt its major communication method. Even after we had completed the design of Version 2 many changes in databases have occurred (e.g., use of common data elements by NCI). Thus, the CHTN is beginning to develop a new version of the TRDMS (Version 3) to take advantage of internet functions more fully and to ensure that the data elements meet new NCI standards for common data elements (CDE's) and hence, permit communication of the TRDMS with other NCI databases. In addition to on-line tissue requests, Version 3 will permit transfer of data from subcontract sites into the database for efficient operations. Another web-based feature may be on line lists of underutilized tissues. In addition a web page may provide educational information, especially answers to frequently asked questions by investigators as well as other educational information, e.g., biohazard updates. The new donor level of Version 3 will also incorporate informed consent and HIPAA authorization requirements as well as NCI/NIH requirements. New features based on recommendations to the computer subcommittee and their review/approval will be added if practicable. Also, as many of the data elements as possible will be common data elements (CDE) as defined by the NCI and the database design will be compatible with communication with investigators and other specimen banking groups including use of encryption. Finally, depending upon the future support of Visual Foxpro it may be necessary to establish Version 3 on a different database platform.

The Ovarian SPORE will operate as a node (division) of the TRDMS and will have all the advantages of future CHTN software developments. Also, the TCBF at UAB is developing a system for bar coding of all specimens and investigator information to reduce errors and improve efficiency.